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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

August 9, 2002

Dockets Management Branch (HFA-305),
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0204, Bar Code Label Requirements for Human Drug Products

To Whom It May Concern:

As part of the initiative of the Secretary of Health and Human Services to reduce medication errors, the Food and Drug Administration (FDA) convened a public meeting to solicit comments for the development of a regulation on bar code labeling for human drug products, including biologic products. The Consumer Healthcare Products Association (CHPA) provided oral remarks as part of an industry panel at that meeting, and takes this opportunity to submit in-depth comments to support and extend its prior position.

Founded in 1881, CHPA represents manufacturers and distributors of nonprescription medicines and dietary supplements, with over 200 members across the manufacturing, distribution, supply, research, and advertising sectors of the self-care industry.

CHPA supports efforts to reduce medication errors, including those that encompass errors in information acquisition by consumers, who are the principal end users of self-care products, and by health professionals as well. An evidence-based description and understanding of issues related to the role of OTCs in medication errors is important in designing any successful solution.

CHPA's comments are framed by two overarching perspectives. First, the OTC setting is different than the professional setting. The OTC setting encompasses self-selection and the vast majority of self-use of nonprescription medicines. In the professional setting, certain OTCs may be recommended by health professionals for use by their patients. Bar coding is used currently on all OTC products. It effectively and efficiently tracks inventory and channels of distribution in the consumer-oriented self-care setting.

The second overarching perspective relates to our concern that regulations without the appropriate evidence-based and economic analyses relating to solutions and the appropriate implementation plans can stifle technological innovation. Potential market-

02N-0204 C12

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based solutions and the ability to leverage existing systems are critical to our industry. Potentially complicated, far-reaching, multi-faceted public health programs should be undertaken with great care after understanding the issues involved.

CHPA's detailed comments relating to this matter focus on the following interrelated positions:

- In the consumer setting, where the vast majority of OTCs are used, Drug Facts labeling is the means designed to address medication errors; bar coding would not add value in this setting.

  In thinking about solutions to medication errors in the institutional setting, as they may relate to OTCs, it should be kept in mind that institutions such as hospitals, comprise a very small part of the OTC market. Hence, any decision to broadly affect all OTC packages with relabeling changes, when only a very small percentage of all OTC packages in certain categories, would be over-reaching in scope and extent.

- The Universal Product Code (UPC) on OTCs is an efficient and effective means to track retail distribution and sales in the self-care retail setting.

- There could be significant potential negative impact to modifying the UPC bar code system used on OTC products.

- FDA should maintain flexibility in how automated identification of medicines might be accomplished, so as to support, not hinder, technological advances.

- If FDA moves forward to require bar coding on drug products, CHPA urges FDA to seek ways to leverage the current UPC bar coding system for nonprescription medicines by linkage of the current UPC on OTC medicines to a national information database.

- In an effort to marshal industry expertise and thinking on how to overcome the significant barriers surrounding this issue, an industry coalition has been formed to address the stakeholder input to this meeting and provide future suggestions on how to move forward in a feasible, practical and cost-efficient way.

Detailed Comments

A. In the Consumer Setting, Where the Vast Majority of OTCs Are Used, Drug Facts Labeling Is the Means Designed to Address Medication Errors; Bar Coding Would Not Add Value in this Setting.

OTC manufacturers and FDA have been mutually concerned about optimizing safe and effective use of OTCs through even better labeling, including ways to minimize medication error in the self-care setting. The nonprescription drug label

provides all the essential information needed for the safe and effective use of the product by consumers on the package in contradistinction to prescription drugs where the information and package are for the most part separate.

Recently, the FDA, in working with other groups including CHPA, developed the Drug Facts Final Rule for improving the content and format of all OTC labels of outer packaging to make essential selection and use information easy to access and comprehend. The Drug Facts regulation dictates the format, order, print size and content of the wording which the lay consumer will receive when they obtain an OTC drug. The Final Rule requires the active ingredient section to appear first among all information in a special box entitled Drug Facts, which also contains directions for usage, warnings (contraindicated medications and contraindicated medical conditions, allergy warnings) and storage information. Lot and expiration date are also required by separate regulations on the outer and inner package. The new Drug Facts labeling is an important step to reduce potential medication errors in the self-care setting as well as the professional setting.

In the development of the Drug Facts box, consideration was given as to how consumers use nonprescription drug products. Access and convenience are key drivers to purchase decisions, and reliance on the consumer reading the OTC label is the principal stratagem for self-care with OTCs. We want and encourage consumers to read the label, understand their medications, and dialogue, when necessary, with a health professional.

It is unlikely that the use of bar codes by consumers in the non-institutional self-care setting is reasonably feasible or preferred over the human readable printed label. Scanners are needed to read bar codes. Consumers do not have hand-held scanners linked to their personal medication records. Further, they most likely don't have the need or desire for such access given their state of health, current medications, and cost and upkeep of what might be envisioned as a personal scanning system.

Finally, in thinking about solutions to medication errors in the institutional setting, as they may relate to OTCs (see also specific comments on bar codes below), it should be kept in mind that institutions such as hospitals, comprise a very small part of the OTC market. Hence, any decision to broadly affect all OTC packages with relabeling changes when only a very small percentage of all OTC packages in certain categories would be over-reaching in scope and extent.

B. The Universal Product Code (UPC) on OTCs Is an Efficient and Effective Means to Track Retail Distribution and Sales in the Self-Care Retail Setting.

Currently all OTC drug products intended for retail sale bear a bar code (Universal Product Code, or UPC) on the outer container. This bar code serves as an effective and efficient means to track channels of distribution, inventory management, and sales by channel of distribution. The vast majority of the 750,000 OTC retail

locations use the UPC to track some 150,000 individual OTC shelf keeping units (SKU's).

One or more other bar codes may appear on the inner surface of the outer package or under an endflap for tracking label inventory and application during production. These codes help prevent a form of medication error caused by label mix-ups during production by assuring that the right label is on the right package before distribution.

The UPC is a unidimensional bar code sytem, providing a number (i.e., like a license plate) which is assigned by the manufacturer for tracking each SKU (shelf keeping unit) through its distribution and sales network. The UPC can be read at high speeds, with a single swipe and at different orientations by flat bed scanners at the check-out counter of some 750,000 retail locations for OTC sales. Since the UPC is a number, it is simply a link to different electronic-based archival systems within distribution centers and retail stores.

C. There Could Be Significant Potential Negative Impact to Modifying the UPC Bar Code System Used on OTC Products.

1. The UPC bar-coding system is a complex system, but it is highly efficient and needed for tracking inventory and managing sales by channel of distribution. No modification of the bar code should be done which would create a negative impact on the basic purpose and success of the current system. For example:

   a. Requiring the UPC to be the NDC would represent a barrier to commerce for OTCs.

      Most often, the UPC on nonprescription medicines is not the NDC number (National Drug Code), which the company assigns and is verified by listing the product with FDA. The reason for this is that UPCs are used to track many types of distribution and sales models of the same product. Multiple different promotions as well as non-promotional retail movements are tracked by UPCs concurrently for each channel of distribution.

      The vast majority of products have more than one size or SKU. While each SKU has its own NDC number, it may have a number of different UPCs (estimated at 1-12) in order to track different modes of distribution and sales for the product (e.g., relating to special labeling relating to promotions, other retailer-specific information or identification for many different retail outlets). Companies need to track SKUs individually in order to assess account sales, promotion success by package size, inventory management, and package tracking in case of product tampering or for a recall. This system is essential for a robust, competitive business environment. The UPC as a national system works extremely well.

Since the UPC is often not the NDC, mandating such linkage would totally disrupt the current system. It would have major impact on sales and distribution systems of small and large businesses and create a several fold increase in drug listing and delisting activities by industry and FDA. The lack of institutional systems to make widespread use of a bar code to reduce medication errors makes the near- to mid-term gain of such a mandate questionable.

b. Adding more than one bar code to the outside of the OTC package will cause confusion and is not recommended by the Uniform Code Council.

Multiple codes have resulted in significant reading errors related to misidentification of products, since bar codes must be read individually. Readers have to sort their responses into channels where information doesn't collide, and this in turn requires further layers of reader technology.

c. Bar coding small OTC packages/blisters is not advisable.

We strongly oppose a regulation that mandates bar coding of small pouches or blister packs of OTC medicines down to the individual unit dose. Inclusion of a bar code on these small packages could necessitate the deletion of package opening instructions needed by the consumer. Mandating bar coding on small packages will force companies to make certain business decisions related to the cost of packaging changes needed to permit bar code printing.

d. The current UPC cannot support the lot number or expiration date.

It is not technically feasible to add the lot number and/or expiration date to the current UPC. Additionally, requiring bar coding of each lot number would create a tremendous burden to the production system for nonprescription drugs and could amplify the potential for label mix-ups. Validated systems are not set up to do on-line bar code printing. Lot information in bar code format may be more critical for insulin products, antineoplastic agents and antiarrhythmic agents than for OTCs in the self care setting.

2. The technology is not yet present that links the UPC on OTC products to a continuously updated information archive accessible broadly to institutions.

Even if a bar coding were to be mandated in the near-term, there is no uniform/standardized national system to convert the numbers represented by the UPC symbol into meaningful information for institutions and to check this information against databases to prevent medication errors. This system needs to be universal, be operational in all the hospitals, nursing homes, etc. with a robust

and validated process to keep this information up to date. Such a system would be complex and very likely resource intensive.

D. FDA should maintain flexibility in how automated identification of medicines might be accomplished, so as to support, not hinder, technological advances.

Bar coding technology and, more broadly auto-identification in all its forms, is expanding, and a regulation should not interfere with this technological advances.

Reduced Space Symbology® (RSS) and Composite Symbology® (CS) represent near-term bar code technology that is supported by major suppliers, who will soon be offering more adaptable and accurate scanners for reduced-size symbology. The OTC industry is very interested in these approaches because they will enhance, not change, the current system. They may concurrently increase the amount of label space available for other important consumer information while expanding the capability of the current tool-set.

Despite significant potential hurdles, radio-frequency devices may soon be feasible and practical to place within packaging. While not viable today for low cost and high volume products such as OTC medicines, such interior packaging systems offer: an increase in the amount of space available for more information links from the auto-identifier; elimination of the need for manual scanning (itself a source of possible error); and simultaneous reading of multiple items.

Other industries are pursuing reduced-sized symbologies, such as RSS and CS, including business sectors seeking to label individual pieces of fruit and CDs. We foresee market pressures accelerating groundswell to evolved reduced symbology. A regulation that interferes with these technological advances will stifle flexibility and disrupt efficient product distribution.

Indeed, given the coming evolution of different types of reduced-size symbologies and identification devices, CHPA believes that terminology used to describe this field should be "automated identification" or "auto-id." It may be that bar coding per se is not the only solution to the issue at hand, and a regulation that locks in a technology could potentially stifle technological expansion.

E. If FDA moves forward to require bar coding on drug products, CHPA urges FDA to seek ways to leverage the current UPC bar coding system for nonprescription medicines by linkage of the current UPC on OTC medicines to a national information database.

Exploring the feasibility of using the current UPC linked to an informational database on labeling could be considered as one possible approach which would likely not disrupt the current tracking of OTC packages in the OTC distribution system. However, we are unaware that such a national database exists, although we

are aware that a CRADA between CDER and Datapharm has been formed to create a national database of NDA labeling for pharmaceuticals. Such a national data base could be accessible to private institutions through the Web.

Summary

In sum, any proposed solution needs to be based on an understanding of the issue as it pertains to OTCs and it must be organized on a national level, to ensure systems compatibility and applicability at reasonable cost and widespread availability. If there are ways to take the current UPC-based system and efficiently apply it to the issue of medication errors, then CHPA is open to and interested in exploring such possibilities. If, however, use of the UPC to address medication errors changes the code's current intended use or its efficiency of use, it will result in significant barriers in distribution channels.

CHPA concurs with the written position of National Coordinating Council for Medication Error Reporting and Prevention that any changes in bar coding requirements should be done incrementally and with careful thought as to feasibility, practicality, and cost-benefit, weighing patient protection, efficiency of proposed systems, and scope.

In an effort to marshal industry expertise and thinking on how to overcome the significant barriers surrounding this issue, an Industry Coalition on Automated Identification of Medicines has been formed to address the stakeholder input to this meeting and provide future suggestions on how to move forward in a feasible, practical and cost-efficient way. Founding members of the Coalition include, alphabetically: Consumer Healthcare Products Association (CHPA), Generic Pharmaceutical Association (GPhA), Healthcare Distribution Management Association (HDMA) and Pharmaceutical Manufacturers Association (PhRMA).

Respectfully submitted by:

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